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Diane Payne on behalf of  
William M. Blackstone

Intervet, Millsboro  
Patent Dept.

302-934-4305

RE: USSN: 10/034,500

Attorney Docket No.: 0-2000.605 US

Please accept the documents, which follow in the above-identified application. The last two pages, being pages ten and eleven of the below Power Point Presentation were not faxed with the rest of the document due to an equipment malfunction.

35 U.S.C. 112, first paragraph and the Wands Analysis Power Point Presentation pages ten and eleven of the presentation (2 pages)

 Intervet

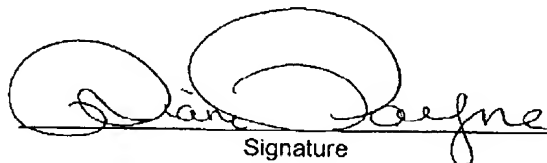
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35 U.S.C. 112, first paragraph and the Wands Analysis Power Point Presentation pages ten and eleven (2 pages)  
Certificate of Facsimile Transmission (1 page)

### Example D (con't)

- Facts:
  - >Some Immunostimulatory oligonucleotide sequences (CpG) are known in the art and are presented in the specification
  - >Specification presents a working example of an art accepted guinea pig model for HSV infection
  - >Art indicates that the guinea pig model, while accurate for studying the development of HSV infection, is not predictive of CpG oligonucleotide sequences that will stimulate an immune response in human individuals

### Example D (con't)

- Enablement determination through the Wands factor analysis may turn on less than all factors
- Here, the specification exemplifies an appropriate animal model...on the other hand, there is evidence that this model is not predictive of therapeutic response
- Other considerations include rate of immune responses stimulated by immunostimulatory oligonucleotide sequences (CpG) resp in prevention as opposed to treatment
- The enablement determination balances all of these considerations.

### Intended Use Limitation

- When a compound or composition is limited by a particular use, enablement of that claim should be evaluated based on that limitation.

See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

37

### Example C

- Consider the following....

- > A viral vector for use in gene therapy comprising:  
a virus comprising a cell binding receptor on the surface thereof  
and a gene of interest, not normally present in the virus, inserted  
within the DNA of the virus.
- > A viral vector comprising:  
a virus comprising a cell binding receptor on the surface thereof  
and a therapeutic gene of interest, not normally present in the  
inserted within the DNA of the virus.
- > A viral vector for delivering a gene of interest to a cell comprising:  
a virus comprising a cell binding receptor on the surface thereof  
and a gene of interest, not normally present in the virus, inserted  
within the DNA of the virus.

38

### Example C (con't)

- Each of the claims on the previous slide contain an intended use:  
 > gene therapy  
 > expression of a therapeutic gene  
 > delivery of a gene of interest into a cell
- The Wands factor analysis continues with determining the scope of the claims.

39

### Example D

- A method for preventing a symptom of herpes simplex virus (HSV) infection in an individual who has been exposed to HSV, comprising administering a composition comprising an immunostimulatory oligonucleotide sequence in an amount sufficient to prevent a symptom of HSV infection.

40